

Telemedicine Enhanced Antidepressant Management (TEAM) Protocol

Overview

The overall structure of the proposed Telemedicine Enhanced Antidepressant Management (TEAM) intervention will follow the multifaceted, stepped-care model of depression treatment originally designed for large urban managed care primary care practices. Through the use of telephone, interactive video, and electronic medical record technologies, this model will be adapted for small rural primary care clinics without on-site mental health staff.

Eligibility for the proposed intervention will be based on the VA Depression Treatment Guidelines recommendations for the treatment of Major Depressive Disorder (MDD) in the primary care setting. To maximize generalizability, only patients requiring specialty care are excluded from the protocol.

Four types of health care professionals will be involved in the TEAM intervention: 1) Primary Care Providers (PCPs), 2) Nurse Depression Managers, 3) Clinical Pharmacists, and 4) Consult Psychiatrists. The PCPs will be located at Community Based Outpatient Clinics (CBOC), and the other three will be located at parent VAMCs. In addition to these four types of TEAM providers, Research Assistants will be responsible for screening primary care patients for MDD.

This intervention, which will target both the patient and the PCP, will have seven main components: 1) academic detailing, 2) screening to establish MDD caseness, 3) patient education/activation, 4) outcomes monitoring and feedback, 5) medication management, 6) psychiatric consultation, and 7) treatment recommendations. The TEAM intervention timelines (see Attachment 1) display the different steps of the intervention and the components associated with each step. Each additional level of stepped care will involve an increasing number of intervention components. The TEAM intervention algorithm (see Attachment 2) shows the decision nodes, potential pathways, and levels of stepped care.

The five steps of care in the acute treatment phase will be 1) watchful waiting with outcomes monitoring, 2) antidepressant therapy through automated treatment recommendation along with medication management and outcomes monitoring, 3) antidepressant therapy recommended by a Clinical Pharmacist along with medication management and outcomes monitoring, 4) antidepressant therapy recommended by a Consult Psychiatrist along with medication management and outcomes monitoring, and 5) referral to the Mental Health Clinic at the parent VAMC for specialty care. Note that TEAM personnel never recommend watchful waiting. Likewise, TEAM personnel only recommend a referral to specialty care for patients eligible for the protocol after three failed antidepressant trials. After assessing the patient's depression severity and

treatment preferences at the index visit, the PCP will decide which of the above steps of care should be initiated as the first line of treatment.

The PCP will face decision points in the TEAM algorithm at several different points along the TEAM timeline (see Attachments 1 and 2). The first decision will occur during the patient's index visit at week 0, when the PCP must decide whether to prescribe recommended antidepressant medications. The next decision points will occur after failed watchful waiting or failed antidepressant trials. Three weeks will be given between the treatment recommendation date and the treatment initiation date so that 1) PCPs can schedule an office visit with patients (if desired), 2) PCPs can sign off on new or adjusted prescriptions, and 3) medications can be mailed to patients.

Depending on PCP choices and patient responses to treatment, there are a large number of potential paths through the treatment algorithm. For example, patients could improve with watchful waiting and remain in remission throughout the remainder of the study (see Timeline 1). In contrast, the PCP and the patient could decide on an initial period of watchful waiting, then the PCP could sequentially prescribe three different antidepressants that are not successful, followed by a referral to the Mental Health Clinic at the parent VAMC (see Timeline 2). A more typical pathway might be having patients that respond to the first antidepressant trial, then have a relapse, followed by a response to a second antidepressant trail (see Timeline 3).

Eligibility

Exclusion criteria will be kept to a minimum because the TEAM protocol will be implemented in routine primary care practice settings. Therefore, consenting patients will be eligible for the protocol unless 1) they have a comorbid condition or depression severity that require specialty care, 2) they have visited a VA mental health clinic within the past 3 months, 3) patients or providers prefer a treatment other than that provided in this protocol, or 4) there are communication problems that prevent the use of telemedicine technology.

Using screening items taken from the Quality Improvement in Depression Study (see Attachment 3), patients will be excluded if they screen positive for an alcohol dependence or bipolar disorder or if their depressive symptoms are due to bereavement. Patients with schizophrenia will be excluded through review of VA pharmacy records to determine if an antipsychotic medication has been prescribed to the patient in the past year. The

Exclusion Criteria

Comorbidity

- Substance dependence disorders
- Bipolar disorder
- Schizophrenia
- Cognitive impairment
- Unstable medical disorders
- Competence

Depression Severity

- Suicidal ideation
- Psychotic Depression
- Due to bereavement

Mental Health Clinic Visit

- Within the past 3 months

Preference

- PCP prefers to refer
- Patient prefers psychotherapy

Communication

- No telephone
- Hearing impairment
- Non-English speaking

Blessed Orientation-Memory-Concentration test (see Attachment 3) will be administered to exclude patients with significant cognitive impairment (those scoring >10 on the test). Patients whose depression puts them at risk for harming themselves (i.e., those with current suicidal ideation) will not be eligible (see Attachment 3). Likewise, if PCPs determine that the patients' medical problems are unstable (e.g., unstable angina, severe emphysema, aggressive cancers, psychotic depression), they will not be eligible for the study. PCPs will also exclude patients who are not competent to make rational informed decisions about their treatment.

Patients will also be excluded if, for any reason, PCPs are not willing to treat their depression in the primary care setting or if, after education/activation, patients report to their PCP that psychotherapy is their preferred treatment alternative. Finally, patients without a telephone or those whose hearing impairment interferes with their use of the telephone will be excluded as well as those unable to communicate effectively in English. In all cases, patients ineligible for the study will be referred to the Mental Health Clinic at the parent VAMC.

Personnel

Four types of providers will be involved in the TEAM intervention. The providers in charge of the patients' care will be PCPs located at CBOCs, who will make all treatment decisions. Because CBOCs are too small to support mental health staff, the other TEAM personnel will be located at the parent VAMC. To exploit economies of scale, TEAM personnel at parent VAMCs will support PCPs providing depression treatment at two CBOC locations.

Primary Care Providers

PCPs located at CBOCs will be responsible for patients' depression care and will authorize all components of the TEAM intervention. These PCPs will also be responsible for excluding patients from the TEAM protocol if patients prefer psychotherapy over pharmacotherapy or if PCPs prefer not to treat patients' depression in the primary care setting. PCPs will be responsible for reading clinical reminders, notes, and medication orders placed in the Computerized Patient Record System (CPRS) by TEAM personnel. These items will contain information concerning screening, outcomes monitoring, treatment recommendations, and medication adherence. PCPs will also be responsible for either electronically or verbally signing off on antidepressant prescriptions recommended by TEAM personnel or through an automated response to the MDD screening.

Nurse Depression Managers

Nurse Depression Managers, who will be registered nurses located at parent VAMCs, will conduct all patient education/activation, outcomes monitoring, and scripted (i.e., structured) medication management. At the time of medication initiation or adjustment, Nurse Depression Managers will telephone patients to explain why antidepressant prescriptions were written or changed, provide instructions for taking medications, discuss expected time to response, identify potential side effects, promote adherence,

and answer questions. In addition, Nurse Depression Managers will be responsible for feeding back information from MDD screening and outcomes monitoring to PCPs via CPRS. If necessary, Nurse Depression Managers will also make appointments for interactive video encounters between patients and Consult Psychiatrists and make referrals to Mental Health Clinics.

Clinical Pharmacists

Clinical Pharmacists, who will be PharmDs located at the parent VAMCs, will supervise the Nurse Depression Managers. They will also be responsible for using the CPRS to review patients' VA medication histories to determine prior antidepressant use/response and to identify currently prescribed medications that are contraindicated for antidepressant therapy. Clinical Pharmacists will review self-reported data, collected during medication management, about non-VA prescriptions and over-the-counter medications. Using guidelines developed for the Texas Medication Algorithm Project (TMAP) (see Attachment 4), Clinical Pharmacists will recommend specific antidepressants and dosages to PCPs using the CPRS. (The initial, automated treatment recommendations that follow a positive screening for MDD will also be based on TMAP guidelines.) Clinical Pharmacists will also use the CPRS to determine whether PCPs have prescribed the recommended antidepressants at the recommended dosages. When PCPs do not follow TEAM treatment recommendations, Clinical Pharmacists will telephone them to discuss these decisions, and if appropriate, to obtain verbal consent to fill the recommended antidepressant prescriptions.

Clinical Pharmacists will also be responsible for ensuring that antidepressant prescriptions are filled and mailed to the patient. When patients are non-adherent or experiencing severe side effects that have not decreased following scripted advice from Nurse Depression Managers, Clinical Pharmacists will telephone patients to recommend additional strategies to minimize side effects. If necessary, they will forward recommended adjunct medications or medication adjustments to PCPs.

Consult Liaison Psychiatrists

Consult Psychiatrists, who will be MDs located at the parent VAMCs, will be responsible for providing consult liaison services to PCPs. Consult Psychiatrists will be specifically responsible for the interactive video encounter(s) with the patients and for providing assistance to Clinical Pharmacists on an as-needed basis. Following the interactive video encounters, Consult Psychiatrists will place treatment recommendations in the CPRS and email or fax treatment recommendations to PCPs. Consult Psychiatrists will also be responsible for telephoning PCPs when these treatment recommendations are not followed to discuss these decisions.

Communication Via Computerized Patient Record System

PCPs located at the CBOC and TEAM personnel located at the parent VAMCs will communicate via CPRS, email, telephone, and fax. Because of its built-in functionality and widespread use throughout the VA, the CPRS will be used as the first line of communication. Specifically, existing features within CPRS will be used to provide screening information, automated treatment recommendations, and treatment

recommendations from the Clinical Pharmacist and Consult Psychiatrist as well as feedback from the outcomes monitoring and medication management components of the intervention.

The Clinical Reminder Package will provide screening information. At the index visit, when PCPs open progress notes for patients screening positive for MDD, the Clinical Reminder Package will display an active (“due”) reminder for addressing the positive screen. Upon opening the reminder, a dialogue box will inform PCPs that patients meet diagnostic criteria for current MDD. In addition, this dialogue box will provide automated treatment recommendations based on TMAP. The dialogue box will list specific antidepressant medications along with guideline concordant dosages and durations. PCPs will be prompted to choose, by “clicking” on a box, a recommended prescription, watchful waiting, or some other treatment regimen. The choice of treatment option will automatically be recorded in the progress note along with space for justifying the decision. If PCPs choose one of the recommended prescriptions, a medication order will automatically be entered in the Active Order Window and flagged for their signatures. When PCPs finish editing progress notes, signed notes will be saved in progress notes windows. Data about depression severity, side effects, and medication adherence will be also be fed back to PCPs by placing standardized reports in separate progress notes (see Attachment 5). Whenever outcomes monitoring indicates significant suicide ideation, the alert screen on the PCPs’ sign-on pages will signal that sentinel markers have been placed in the patients’ progress notes.

Whenever TEAM personnel need to make subsequent treatment recommendations that are not associated with the index visit, the alert screen on the PCPs’ sign-on pages will notify them that clinical reminders have been placed in patients’ progress notes recommending new antidepressant medications. Once again, PCPs choosing one of the recommended prescriptions will have a medication order entered into the Active Order Window. PCPs will be prompted to sign the medication orders prior to exiting CPRS or selecting new patients. Once PCPs sign the medication orders, notifications on the alert screen will be removed. All TEAM personnel will have access to the CPRS so they can review patients’ progress notes and medication orders.

Components

Academic Detailing

Consult Psychiatrists and Clinical Pharmacists at parent VAMCs will travel to meet with PCPs at the CBOCs to educate them about MDD and the TEAM protocol. During this Academic Detailing, PCPs will be given the TEAM intervention protocol, the VA Depression Treatment Guidelines, and the TMAP Manual on which the TEAM intervention is based. Academic detailing materials will also include educational materials developed for the Partners in Care Study, including the *Clinical Guide to Depression Assessment and Management in Primary Care* and *Quick Reference Cards* (see Attachment 6). Academic detailing will be divided into two sessions, each counting for Continuing Medical Education (CME) credit. The first session will focus on MDD and its prevalence, incidence, and natural course of history as well as on VA Depression Treatment Guidelines. The second session will focus on the TEAM protocol and the

TMAP Manual. PCPs who miss the academic detailing sessions will be given one-on-one training.



MDD Screening

Research Assistants located at the Little Rock VAMC will screen all patients with an encounter at the CBOC. Patients will be administered the depression module of the Prime-MD Patient Health Questionnaire (PHQ) over the phone two weeks prior to the scheduled appointment to establish caseness. The 9-item PHQ asks about the frequency of depression symptoms in the past 2 weeks (see Attachment 7). Note that the timing of administration, the mode of administration, and the location of the administrator can be altered without having an adverse impact on the screening component of the TEAM protocol.

For those patients screening positive, notes will be placed in the CPRS to notify their PCPs. These patients will be asked to participate in the TEAM protocol and to provide information about past/current use of antidepressants and current use of other medications. In addition, patients will be asked about the quantity times frequency (QXF) of alcohol consumption in the past month.

MDD Screening Criteria/ Depression Severity

Current depression severity, or severity in the past 2 weeks, will be determined using the Prime-MD PHQ-9, which ranges from 0 to 27. Depression severity is categorically defined as:

none—score ≤ 5

mild— $5 < \text{score} \leq 10$

moderate— $10 < \text{score} \leq 15$

major— $15 < \text{score} \leq 20$

severe—score > 20

A cutoff score of 11 will be used to identify patients with MDD. Using 11 as the cutoff, the PHQ-9 has 94% specificity and 99% sensitivity compared to clinical assessment.



Patient Education/Activation

After a positive screen for MDD, patients will be mailed educational materials concerning depression that were developed for the Partners in Care Study. Materials will include a videotape written and narrated by a VA psychiatrist and a short brochure highlighting the video's important points (see Attachment 8). The educational materials will describe depression, its symptoms, its causes, its natural course of history, and available treatments. In addition, following the Partners in Care model, Nurse Depression Managers will telephone patients before their index visits to 1) answer questions about the study, 2) provide additional patient education regarding depression and depression treatment, and 3) encourage patients to discuss their depressive symptoms with their PCPs during their upcoming CBOC visits. Specifically, nurses will help patients identify two questions about depression to ask PCPs.



Outcomes Monitoring and Feedback

Nurse Depression Managers will conduct outcomes monitoring over the telephone. After each occurrence of outcomes monitoring, a progress note will be placed in the CPRS, tracking the patient's depression severity over time and classifying the patient's current severity level (see Attachment 5). Depression severity will be monitored from patient self-report using the PHQ-9 module from the PRIME-MD (see Attachment 9 and the box on the previous page). The PHQ-9 is a very brief 9-item instrument that identifies the number and frequency of depression symptoms experienced during the previous 2 weeks. The PHQ-9 was designed for assessing depression severity in routine primary care practice settings.

Outcomes monitoring will be conducted every 4 weeks for patients in the *watchful waiting* step of treatment. It will be conducted every 2 weeks for patients in the *acute phase* of treatment, which is defined as the time period following the initiation of an antidepressant trial and preceding a full response. If a full response to treatment has not occurred within 8 weeks of initiating an antidepressant trial, care will be stepped up and a revised treatment recommendation will be made. To maximize patient safety, the level of care will also be stepped up if any outcomes monitoring encounter indicates that depression severity is 5 points higher than at the initiation of the antidepressant trial or watchful waiting. Patients with current suicidal ideation and plan will be immediately referred to the Mental Health Clinic at the VAMC.

Response to Treatment

Response to treatment will be divided into four categories based on change in depression severity during the 8-week antidepressant trial.

No response—<0% reduction in symptom severity.

Minimal response—0%-25% reduction in symptom severity.

Partial response—25%-50% reduction in symptom severity and a symptom severity score >5.

Full response—50%-100% reduction in symptom severity or a severity score ≤5.

Outcomes monitoring will be reduced to every 4 weeks for patients in the *continuation phase* of treatment, which is defined as the 6 months of treatment following a full response to an antidepressant trial. Patients in this phase of treatment will be followed monthly for 6 months or until 52 weeks since the index visit, whichever comes first (the TEAM intervention will terminate after one year).

Patients who experience a *relapse* during the continuation phase of treatment will have their care stepped up, a revised treatment recommendation will be made, and outcomes monitoring will be increased to every 2 weeks.

Relapse

Relapse following a full response is defined as having symptom severity >50% of baseline severity or a severity score ≥10.



Medication Management

For those in the acute phase of antidepressant therapy, the biweekly telephone contacts for outcomes monitoring will also involve medication management. Medication management will be the responsibility of Nurse Depression Managers and Clinical Pharmacists. Medication management will begin after the prescription is filled, but before patients receive medications in the mail. Nurse Depression Managers will telephone patients to 1) explain why prescriptions are written/changed, 2) provide instructions for taking medications, 3) discuss the expected length of time to response, 4) identify potential side effects, 5) promote medication adherence, and 6) answer questions about the medications. From the time that patients receive medications in the mail, there will be 8 weeks of medication management, based on the Telephone Care Manager Program implemented at Group Cooperative Health in Seattle (see Attachment 10).

Following a structured script, Nurse Depression Managers will assess current medication use, as well as the presence and severity of antidepressant medication side effects. Nurse Depression Managers will also follow a structured script to identify problems with treatment adherence, including 1) discontinued use of medication, 2) taking less than the prescribed dose, 3) taking medication less frequently than prescribed, or 4) severe antidepressant side effects such as patient reports that they will be unable to continue taking medications unless side effects improve. For non-compliant patients, Nurse Depression Managers will ask about reasons for non-adherence. Patients who are non-adherent or at high risk for non-adherence because of severe side effects will be administered a semi-structured protocol (see Attachment 10) to address common problems with adherence and/or side effects.

Nurse Depression Managers will place information about side effects and adherence in the CPRS for PCPs at CBOCs. Clinical Pharmacists will review the medication management reports to identify problems with side effects or adherence. If patients are 1) experiencing severe side effects, 2) not taking the full dosage, or 3) not taking the medication for 1 or more days per week (<80% adherence), Clinical Pharmacists will telephone patients and suggest strategies to deal with side effects and promote adherence. If patients continue to experience severe side effects or are non-adherent because of side effects at the next outcomes monitoring/medication management contact 2 weeks later, Clinical Pharmacists will recommend changes to the antidepressant prescriptions.



Psychiatric Consultation

If necessary, Nurse Depression Managers will make appointments for patients to have interactive video consultations with Consult Psychiatrists who will provide new treatment recommendations to PCPs. Using dedicated VTEL Desktop SmartStations at both CBOCs and parent VAMCs, interactive video encounters with two-way video between patients at CBOCs and Consult Psychiatrists at parent VAMCs will be initiated. If

requested by Consult Psychiatrists, additional appointments for tele-psychiatry encounters will be scheduled. The content of interactive video encounters with Consult Psychiatrists will be as similar as possible to the content of face-to-face psychiatric consultations. After assessing patients, Consult Psychiatrists will make treatment recommendations to PCPs. Treatment recommendations will be made by Consult Psychiatrists using the CPRS, followed-up after a week by telephone calls from Consult Psychiatrists to PCPs if recommended medication orders have not been co-signed.

Treatment Recommendations

PCPs will receive all treatment recommendations in the CPRS. Treatment recommendations will either be automated or generated by TEAM personnel located at parent VAMCs. All treatment recommendations will be based on VA Depression Treatment Guidelines and the TMAP Manual (see Attachment 4). Table 1 from TMAP summarizes antidepressant dosing by category of antidepressant. Regardless of the source of the *recommendation*, PCPs will ultimately make all treatment *decisions*, choosing either to 1) prescribe the recommended antidepressant, 2) initiate a period of watchful waiting, or 3) initiate an alternative treatment regimen. Treatment recommendations will be made at specific decision nodes outlined in the TEAM Algorithm (see Attachment 2). At each decision point, treatment recommendations will depend on clinical information collected during the screening, outcomes monitoring, and medication management components of the protocol. Relevant clinical information will include 1) current use of medications other than antidepressants, 2) prior use of antidepressants and response, 3) response to current antidepressant trials, 4) adherence to current antidepressant trials, and 5) side effects of current antidepressant trials.

Initial Treatment Recommendation

1. *Patients without current antidepressant prescriptions.* If patients are not currently being prescribed an antidepressant, the automated treatment recommendation will be to prescribe a selective serotonin reuptake inhibitors (SSRI) (see TMAP Table 1 in Attachment 4). The automated recommendation in the CPRS will list specific SSRIs and starting dosages for this first 8 week antidepressant trial.
2. *Patients with current antidepressant prescriptions.* There will be two possible treatment recommendations for patients who are taking antidepressant medications at the time of screening, but still meet eligibility criteria for major depression. If the patient has been taking an antidepressant for at least 6 weeks and the severity of depression is moderate to severe (score>10), the automated treatment recommendation will be to switch to another antidepressant. If the severity of depression is none to mild (score≤10), the recommendation will be to continue current treatment. If the patient has a current antidepressant prescription, but they are not adherent, the automated treatment recommendation will be to switch to another antidepressant.

Revised Treatment Recommendations

Revised treatment recommendations will be made by Clinical Pharmacists or Consult Psychiatrist using the CPRS through reminders that will be activated each time PCPs use the system. If PCPs have not signed off on new or initial prescriptions within a week and have not written a note describing reasons for not prescribing an antidepressant or changing the antidepressant medication dosage, Clinical Pharmacists or Consult Psychiatrists will telephone PCPs to discuss the rationale for their decisions. If PCPs indicate that appointments have been made for patients at the CBOCs to discuss antidepressant therapy, Clinical Pharmacists or Consult Psychiatrists will wait until after the visits before telephoning PCPs. If PCPs verbally or electronically sign off on new prescriptions, Clinical Pharmacists will ensure that prescriptions are filled and mailed to patients and that medication management is initiated.

Non-Adherent Patients. The potential treatment recommendations for patients who fail an antidepressant trial because of non-adherence will include 1) switching medications, 2) adjusting the dosage, or 3) augmenting the antidepressant prescription with medications to alleviate side effects.

Non-Adherence Criteria

Not taking the full dosage
Not taking the medication for 1
or more days per week

Non-Responsive Patients. The potential treatment recommendations for patients who fail an antidepressant trial because of lack of response after 8 weeks include 1) switching medications; 2) adjusting the dosage; or 3) refer patient to interactive video with Consult Psychiatrists.

Steps of Care

To optimize the cost-effectiveness of the TEAM protocol, the treatment algorithm and timeline follow a stepped-care model. Patients failing to respond to the current level of treatment after 8 weeks will be stepped up to the next level of care. Each additional level of care will require an incremental allocation of resources. Once full responses are achieved in the acute treatment phase, treatment intensity will be reduced during the continuation phase of treatment.

Acute Treatment Phase

1. Watchful Waiting and Outcomes Monitoring

The first step of care may be watchful waiting. PCPs may opt for watchful waiting for a number of reasons, including 1) PCPs may be unaware that patients screened positive for MDD and opt for watchful waiting by default; 2) patients may have more urgent medical problems that need to be addressed during primary care visits; 3) patients may refuse to take antidepressant medications; and/or 4) PCPs and patients may decide together to postpone medication treatment because significant psychosocial stressors are easing or patients want more time to learn about treatment options. During this period, Nurse Depression Managers will conduct outcomes monitoring using the telephone every 4 weeks. Results will be fed back to PCPs using the CPRS. If

watchful waiting is unsuccessful, the level of care will be stepped up to antidepressant therapy and medication management. Watchful waiting will be considered to have failed if 1) depressive severity has increased by 5 points at the 4-week outcomes monitoring encounter or 2) there has not been a full response after 8 weeks.

2. Antidepressant Therapy in Response to an Automated Treatment Recommendation with Medication Management and Outcomes Monitoring

The second step of care is antidepressant therapy recommended through an automated note in the CPRS for patients whose depression severity is ≥ 11 according to the PHQ-9. These recommendations to PCPs will be based on TMAP guidelines. If the prescription is filled, Nurse Depression Managers will telephone patients to discuss prescriptions and answer questions. Initial medication management encounters will then be followed by 8 weeks of biweekly outcomes monitoring and medication management. Outcomes monitoring via the telephone will be conducted by Nurse Depression Managers every 2 weeks, with treatment response assessed at 8 weeks. After administering the outcomes assessment instrument, Nurse Depression Managers will administer the medication management protocol. If at any time side effects are severe or patients are non-adherent because of side effects, Nurse Depression Managers and, if necessary, Clinical Pharmacists will call the patient to promote adherence and/or suggest strategies to minimize the impact of side effects. The antidepressant trial will be considered to have failed if 1) patients are non-adherent because of side effects or they experience severe side effects at two consecutive medication management encounters, 2) depressive severity has increased by 5 points at an outcomes monitoring encounter, or 3) there has not been a full response after 8 weeks.

3. Pharmacist-Recommended Antidepressant Therapy with Medication Management and Outcomes Monitoring

The third step of care will occur after the first failed antidepressant trial. At this point, Clinical Pharmacists, using the TMAP guidelines, will recommend switching, adjusting or augmenting antidepressant prescriptions to PCPs. In this step, the TEAM protocol will also include 8 weeks of outcomes monitoring and medication management by Depression Nurse Managers and Clinical Pharmacists.

4. Consult-Psychiatrist-Recommended Antidepressant Therapy with Medication Management and Outcomes Monitoring.

In the fourth step of care, which occurs after a second failed antidepressant trial, appointments will be made for interactive video encounters between patients and Consult Psychiatrists. After assessing patients and reviewing their adherence, side effects, and response to previous antidepressant trials, Consult Psychiatrists will recommend new prescriptions based on TMAP guidelines. As before, the TEAM protocol will call for 8 weeks of biweekly outcomes monitoring and medication management by Nurse Depression Managers and Clinical Pharmacists. If patients fail a third antidepressant trial, the level of care will be stepped up to referral to parent VAMC Mental Health Clinics.

5. Referral to Mental Health Clinic

After three failed antidepressant trials, the final step of care will be to refer patients to specialty mental health treatment at parent VAMCs. Nurse Depression Managers will make appointments for patients at Mental Health Clinics. After initial in-person assessments, specialty mental health care providers at parent VAMCs will have the option to continue in-person visits or use a mixture of in-person and interactive video visits using the telemedicine equipment at CBOCs and parent VAMCs.

Continuation Treatment Phase

Outcomes Monitoring

For patients experiencing full responses after 8 weeks of an antidepressant trial, care will be stepped down. The frequency of outcomes monitoring will be reduced from every 2 weeks to every 4 weeks. Results will continue to be fed back to PCPs using the CPRS. If patients relapse in the continuation phase of treatment, care will be stepped up to the level that is one step above the step that led to the full response. If no relapses occur, outcomes monitoring will be terminated after 6 months or 52 weeks after the index visit with PCPs, whichever comes first.

Decision Nodes

Whenever watchful waiting or antidepressant therapy fails, the decision will be made to step up the level of care and/or make treatment recommendations. The decision nodes will occur at 1) the index visit, 2) outcomes monitoring encounters, 3) medication management encounters, 4) the completion of watchful waiting (if chosen by PCP and patient), and 5) the completion of an antidepressant trial. The exact week along the TEAM timeline during which treatment recommendations will be implemented depends on the time required for 1) patients to visit PCPs to discuss depression treatment, 2) PCPs to sign off on recommended antidepressant prescriptions, and 3) prescriptions to be filled and mailed to patients. The next highest level of care will depend on whether the decision node occurs during the index visit; watchful waiting; or the first, second, or third antidepressant trials.

Index Visit

If the decision node occurs during index visit, an automated notice will be placed in the CPRS to recommend the initiation of antidepressant therapy (step 2).

Watchful Waiting

If the decision node occurs at the end of the watchful waiting period, TEAM personnel will recommend initiating antidepressant therapy and stepping up care from level 1 to level 2.

First Antidepressant Trial

If the decision node occurs during the first antidepressant trial, the level of care will be stepped up from level 2 to level 3 and the Clinical Pharmacist will recommend specific changes to the antidepressant prescription.

Second Antidepressant Trial

If the decision node occurs during second antidepressant trial, the level of care will be stepped up from level 3 to level 4, and the Consult Psychiatrist will recommend specific changes to depression treatment.

Third Antidepressant Trial

If the decision node occurs during a third antidepressant trial, the level of care will be stepped up from level 4 to level 5 in which TEAM personnel recommend referral to the parent VAMC Mental Health Clinics for further treatment.

Potential Treatment-Response Trajectory

Patients' episode of care trajectories through the TEAM algorithm and timelines will depend on choices made by PCPs and the adherence and response of patients to antidepressant therapies. Three possible trajectories are displayed in the timelines contained in Attachment 1.

Successful Watchful Waiting

The first timeline represents the trajectory of a hypothetical episode of care in which PCPs and patients choose watchful waiting (step 1), and patients fully respond to watchful waiting. Based on the TEAM protocol, these patients would have received screening, patient education/activation, and outcomes monitoring every 4 weeks for 6 months until week 24.

Response-Relapse-Response

The second timeline represents the trajectory of a hypothetical episode of care in which PCPs decide to initiate antidepressant therapy (step 2) at index visits, patients fully respond after 8 weeks of antidepressant treatment, and then patients relapse 3 months later. Based on the TEAM protocol, these patients would have received screening, patient education/activation, and then outcomes monitoring and medication every 2 weeks for 8 weeks. Given a full response at the end of the first antidepressant trial, outcomes monitoring would have been decreased in frequency to every 4 weeks until relapse 3 months later. After relapsing, patients would be stepped up to level 3 and outcomes monitoring and medication management would increase in frequency to every 2 weeks for the next 8 weeks of modified antidepressant treatment. Given a full response at the end of the second antidepressant trial, the frequency of outcomes monitoring would be reduced to every 4 weeks and terminated in week 52.

No Response

The third timeline represents the trajectory of an episode of care in which PCPs and patients first choose watchful waiting and then PCPs prescribe antidepressant medications as recommended by the TEAM personnel. However, in this scenario, patients do not fully respond to any recommended treatments. Based on the TEAM protocol, patients would have received screening, patient education/activation, and then outcomes monitoring every 4 weeks for the 8 weeks of watchful waiting. Given a non-

response to watchful waiting, TEAM Clinical Pharmacists will follow-up on the automated treatment recommendation, first by placing a clinical reminder on the alert screen of the CPRS and, if necessary, by phoning the PCP. After PCPs electronically or verbally sign off on the recommended antidepressant prescriptions, patients would receive outcomes monitoring and medication management every 2 weeks for the 8 weeks of the first antidepressant trial. Given a non-response after 8 weeks of the first antidepressant trial, PCPs would then sign off on new prescriptions recommended by Clinical Pharmacists. Patients would receive outcomes monitoring and medication management every 2 weeks for the 8 weeks of the second antidepressant trial. Given the non-response after 8 weeks of the second antidepressant trial, patients would meet with Consult Psychiatrists, and PCPs would sign off on new prescriptions recommended by Consult Psychiatrists. Patients would receive outcomes monitoring and medication management every 2 weeks for the 8 weeks of the third antidepressant trials. Given a non-response after 8 weeks of the third antidepressant trial, patients would be referred to Mental Health Clinics at parent VAMCs at approximately week 40. If patients or providers request visits at the CBOC to discuss each TEAM treatment recommendation, the referral may occur as late as week 48, allowing an additional 2 weeks for each of the four visits. Outcomes monitoring and medication management would be terminated after referral to parent VAMC Mental Health Clinics.